# MICROLIGHT ML 830® LASER SYSTEM

## OPERATING GUIDE

CAUTION: Federal (or United States) Law restricts this Device to sale by or on the order of a Licensed Clinician.

CAUTION: Laser Radiation. Avoid Direct Eye Exposure. Do Not Stare into Laser Beam.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation on exposure.

See U. S. Patent No. 5,464,436

MICROLIGHT CORPORATION OF AMERICA

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Lit001/Rev.F

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# MICROLIGHT ML 830® LASER SYSTEM

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# MICROLIGHT ML 830® LASER SYSTEM

CAUTION: Federal (or United States) Law restricts this Device to sale by or on the order of a Licensed Clinician.

WARNING AND CAUTION

Before connecting the Recharger Console Unit or operating the ML 830® Laser read the Warning and Safety Instructions in Section 3. Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation on exposure.

## 1. INTRODUCTION

Welcome to the MicroLight Corporation's ML 830® Laser System. This Operating Guide will lead you through the steps for operating the ML 830®. Please proceed through this Guide by following the steps in sequence.

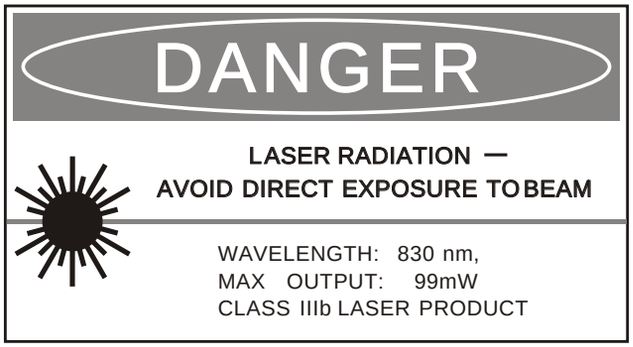
## 2. COMPONENTS

The ML 830® Laser System comes with the following components. If any item is missing or damaged, immediately call your dealer, or call MicroLight Corporation at 281-433-4648.

- Recharger Console Unit
- Rechargeable Batteries (3)
- System Carrying Case
- Probe Carrying Case
- Model 830 Laser Probe
- Safety Glasses (2 pair)
- Power Cord
- Keys

## 3. WARNINGS AND SAFETY INSTRUCTIONS

Before you begin using your ML 830® Laser or the Recharger, read these important warnings and safety instructions. For your own safety and that of your equipment, take note of the following:



Warnings:

- The Recharger must be grounded. Connection to a non-grounded electrical outlet is unsafe. The Warranty covering this unit is null and void if the Recharger is connected to a non-grounded electrical outlet.
- Wear safety glasses to filter out 830nm infrared energy.
- Do not aim the laser beam directly into the eye(s). The lens of the human eye can focus the 830nm wavelength beam, resulting in retinal burn and / or vision problems.
- When the ML 830® Laser System is unattended, all three batteries must be removed and stored in the safety compartment in the base of the Recharger Unit. This compartment must be locked and the key kept by the authorized user.

Safety Instructions:

Disconnect the power plug ( by pulling on the plug, not the cord ) under the following circumstances:

- If the power cord or plug becomes frayed or otherwise damaged.
- If anything is spilled into the equipment, & see page 3.

- If your equipment is exposed to rain or any other excessive moisture.
- If your equipment is dropped or the Recharger case is damaged.
- If you suspect that your Recharger needs repair or service.
- Whenever the Recharger is not in use.
- Whenever power surges are expected, such as during thunderstorms or power outages.

## 4. SETTING UP THE RECHARGER

- Plug in the Recharger. Connect the main power cord to the power inlet socket on the rear of the Recharger (Figure 1). Connect the main plug to a grounded electrical outlet. Be sure that the electrical outlet is grounded to the main breaker box.
- Switch the unit on at the power switch. The power display meter (Figure 2) will illuminate and read "00".

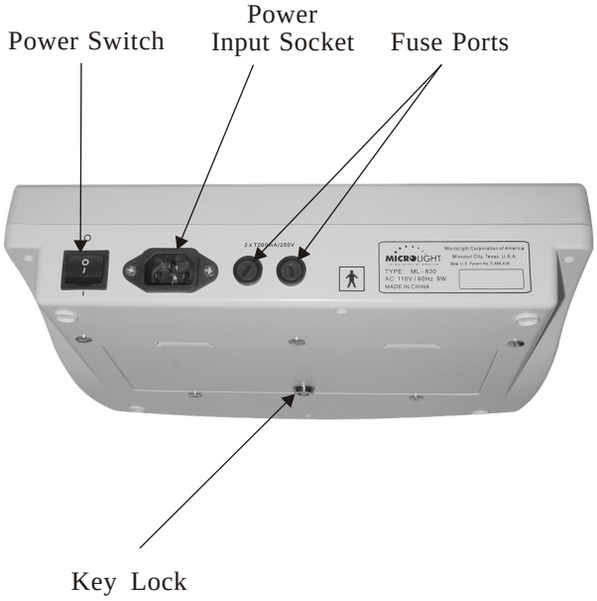



Figure 1

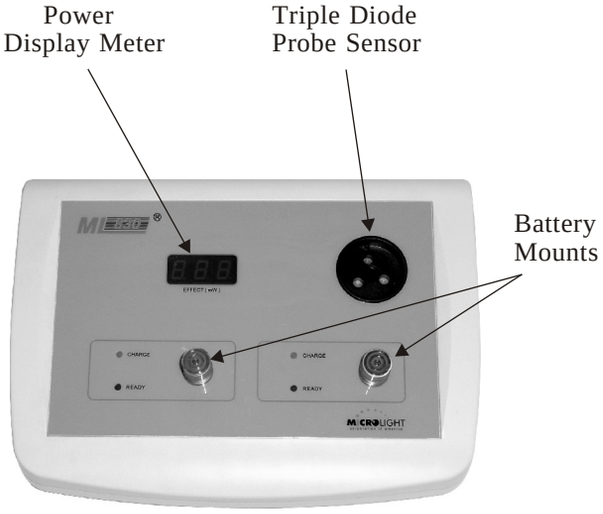


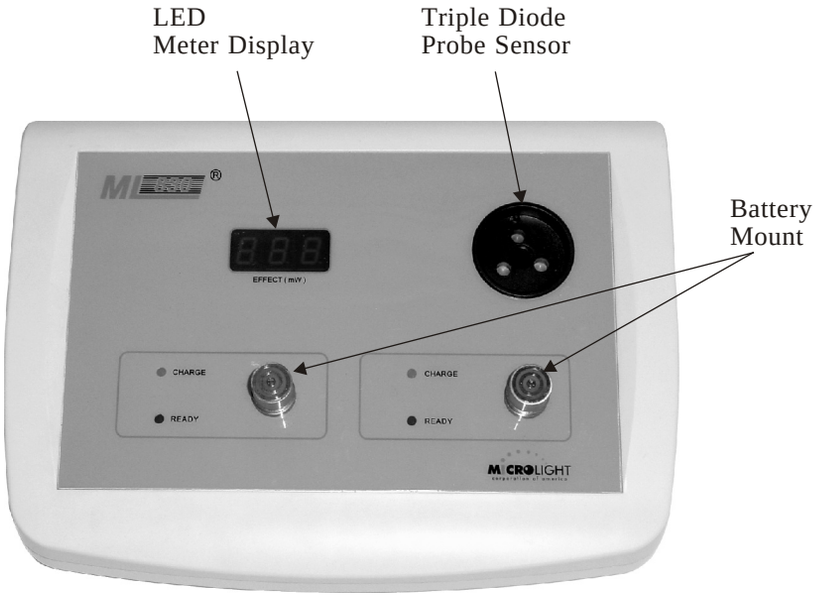

Figure 2

## 5. TESTING THE POWER OUTPUT

- Connect the rechargeable battery to the ML 830® Laser probe by carefully threading the battery onto the threaded end of the laser probe. (Be careful not to strip the threads.) Thread the battery until resistance is felt then tighten one-half turn. Do not over tighten.

- The LED meter on the Recharger measures the laser energy output of the ML 830® Laser. There is a probe sensor (Figure 3) on the Recharger located to the right of the LED meter for the triple diode laser probe.

- Place the head of the ML 830® Laser probe into the probe sensor port and gently hold the probe steady during testing. When testing the laser probe, note the 'notch' on the head of the laser probe and line up the 'notch' with the register pin in the probe sensor port (Figure 4)




Recharger Front

Figure 3

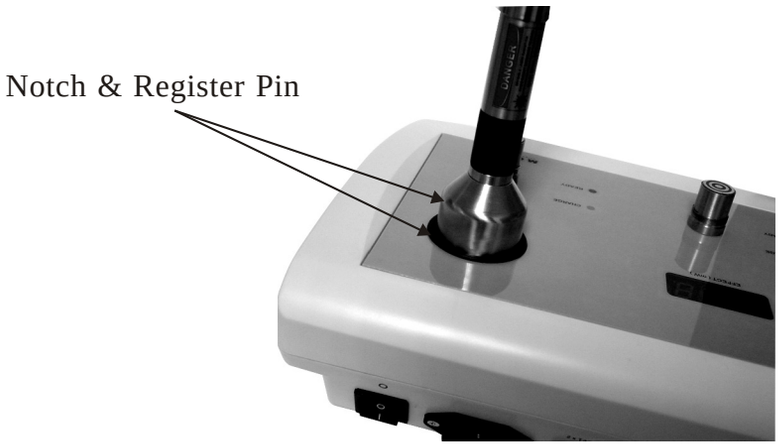



Figure 4

- Note the LED meter reading. Output is measured in milliwatts (mW). The meter should read 90mW(+/-10%).

- Activate the laser's annular or tactile (on-off) switch (Figure 5). [The switch is located beneath the black vinyl area on the laser probe which surrounds the entire probe.] By gently squeezing, the switch will be activated, turning the power on. This also activates an audible acoustic "beep" at half-second interval which continues for 33 seconds. (Note: At the conclusion of the 33-second cycle, there is a short continuous tone.)

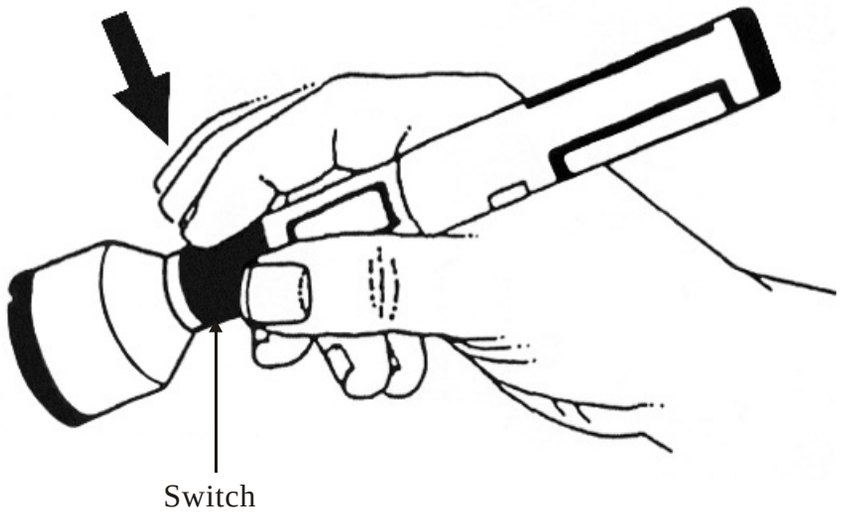



Figure 5

## 6. CHARGING THE BATTERIES

- Carefully unscrew the battery from the laser probe unit (Figure 6),

Figure 6

- Carefully thread the battery onto one of the battery mounts (Figure 7), but only until finger tight.

Figure 7

NOTE: Batteries should each be charged at least twelve (12) hours before initial use or after long periods of nonuse.

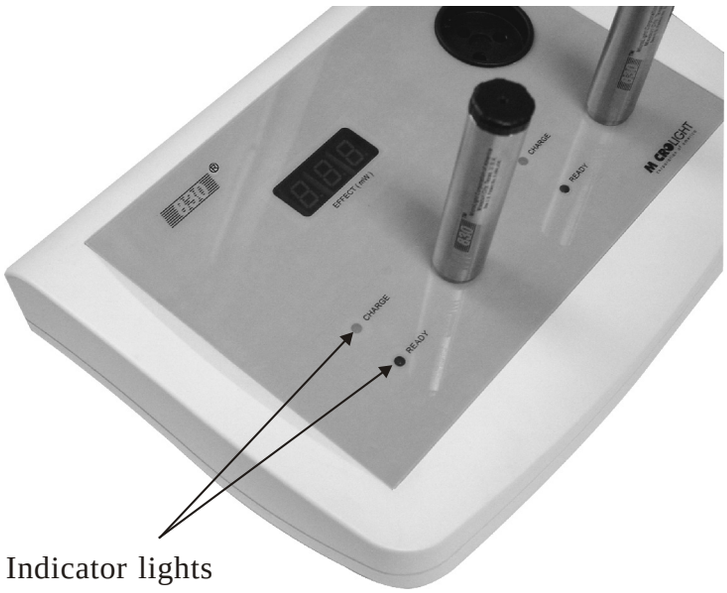



Figure 8

- Note the Illuminated Indicator lights on the left of the battery mount (Figure 8).
- The "CHARGE"Indicator Illuminates when the battery is being charged.
- If the battery is left attached to the battery mount, the battery will continue to be charged at low current. 100% capacity will be reached after 10 hours of charging.

NOTE:

If a fully charged battery is removed from the battery mount and then replaced, the "CHARGE" light will illuminate for a short period of time. Likewise, switching OFF the Recharger briefly, with the battery affixed, then switching the Recharger on again will cause the "CHARGE" light to illuminate for a short period of time.

## 7. OPERATING THE LASER

- Warning: Do not aim the laser beam directly into the eye(s). The lens of the eye can focus the 830nm wavelength beam, resulting in retinal burn and / or vision problems. Wear the safety glasses provided with the unit during use.

- Automatic laser activation cycle is 33 seconds. This safety activation mechanism is built into the unit to ensure the highest level of safety for the end user. During the 33-second cycle you will hear an acoustic "beep" at half-second intervals.

  One 33-second cycle administers approximately one joule of energy per diode according to the following formula:

  Energy(joule)=Mean Power(W) x Time (sec.)
  Energy = 30mW x 33 sec. = 0.99 joule

- Activate the black annular or tactile switch on the laser probe. (Figure 5). Once the switch is pressed, the laser is activated one (1) 33-second cycle or until the switch is lightly depressed again.

## 8. USE OF THE REMOTE INTERLOCK

- MicroLight provides a remote interlock for use in those rare situations where the operator wishes to terminate the emission of low-level laser energy when a door or portal into the area of usage is opened. Call your Microlight dealer for assistance on this module.

- The remote interlock module, if used, requires unscrewing the battery from the laser probe, screwing on the remote interlock onto the laser probe, and then replacing the battery to the open end of the interlock.

- Select a switch, or microswitch, that can be operated by the opening of the door or other portal for which the interlock function is desired. The switch should be electrically open when the portal is open and electrically closed when the portal is closed.

- Connect the switch across the two (2) conductors at the other end of the interlock cable and mount the switch so as to be operated by the opening of the portal as described above. The laser can then be operated when the portal is closed and will be inoperable when the portal is open.

## 9. PRINCIPLES OF OPERATION

The activating switch is located beneath the black vinyl area surrounding the entire circumference of the laser probe. By gently squeezing, the switch will be activated, turning the power on. This also activates an audible "beep" at half-second intervals which continues for 33 seconds. At the conclusion of the 33-second cycle, there is a short continuous tone and the cycle is deactivated.

It is important to check the power output of the laser on a periodic basis to ensure that the laser is functioning properly and has not been damaged by handling. Plugging in the Recharger does this. Connect the main power cord to the power inlet socket on the rear of the Recharger (Figure 1). Connect the main plug to a grounded electrical outlet. Be sure that the electrical outlet is grounded to the main breaker box. (The plug should be removed from the outlet when the recharger is not in uses.)

Switch ON the unit at the power switch. The power display meter (Figure 2) will illuminate and read "00".

Activate the laser switch. By gently squeezing, the switch will be activated, turning the power on. This also activates an audible acoustic "beep" at half-second intervals which continues for 33 seconds. Note the LED meter reading. Output is measured in milliwatts(mW). The meter should read 90 mW (+ /- 10%). If the value is within the limits the unit is ready for use.

The ML 830® Laser is programmed with an "automatic" laser activation cycle of 33 seconds. Once the switch is depressed the laser automatically stays on for 33 seconds or until the switch is lightly depressed again. No further pressure is required to continue the cycle. Each cycle administers approximately one joule of energy per diode according to the following formula:

Energy(joule) = Mean Power (W) x Time (sec.)

Energy = 30mW x 33 sec. = 0.99 joule

To begin a new cycle the switch must be depressed again. During treatment and administration of each 33-second cycle, the laser should be held still to allow full absorption of photons available to the target site. The triple diode laser, due to its configuration should be kept on the same spot for a completed cycle and rotated 40 degrees between each cycle. By rotating the laser, the target area will be more thoroughly treated.

The MicroLight ML 830® system utilizes three semiconductor laser diodes, each diode emitting approximately 30 milliwatts continuous wave at an 30 nanometer wavelength. It is an infrared gallium - aluminum - arsenide laser. The device automatically turns off 33 seconds after activation and each operation of the laser delivers approximately 1 joule of energy per diode. There are no user adjustments or user serviceable features. Only recharging of batteries and periodic verification of power output are to be performed the user.

The ML 830® laser probe generally will require a recharge of batteries after about 50 - 100 cycles. The unit will continue to output the proper milliwatts of power to the point of depletion; however, the 33-second cycle will be interrupted should the battery power become too low. Depleted batteries should be recharged.

To recharge the batteries unscrew the battery from the laser probe and thread the battery onto one of the battery mounts on the Recharger Unit. A "CHARGE" indicator light will illuminate when the battery is being charged. A full charge to 100% capacity requires about 10 hours of charging.

10. INDICATIONS FOR USE:

The MicroLight ML 830® Laser is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

11. ML 830® STUDY

In 1998, the ML 830® was utilized in a double blind study to determine the efficacy of low level lasers in the treatment of Carpal Tunnel Syndrome. The study protocol targeted approximately 135 patients diagnosed with carpal tunnel syndrome with moderate to severe symptoms, with a mean Symptom Severity Scale score of at least 2.0, with a score of at least 30 on a 100 point VAS pain scale, who have failed conservative therapy for at least one month and who have not had previous carpal tunnel release surgery. One-half of the study subjects received treatment with an active the ML 830®, and one-half received treatment with a placebo ML 830®.

Patients were treated three times a week for five weeks. Follow up times were 1, 6, and 12 weeks after the last treatment, at which time information was recorded on each patient. Once the study was completed, a statistical analysis was performed on the active and placebo groups.

Treatment was considered successful if a patient showed a 30% or more reduction in VAS pain score at the 12-week follow-up point. By this definition, the ML 830® laser successfully treated 55.8% of the patients in the active group, compared to 40.0% success for patients in the placebo group. No adverse effects from the ML 830® treatment were noted.

| | Percent of Patients | |
|---|---|---|
| IMPROVEMENT | MicroLight | Placebo |
| Any | 75.6% | 69.3% |
| 30% or more | 55.8% | 40.0% |
| 50% or more | 45.3% | 29.3% |

12. CONTRAINDICATIONS:

Use of the ML 830® is contraindicated where analgesia may mask progressive pathology, and should not be used where the practitioner would normally avoid the use of any other analgesia in order to retain beneficial aspects of pain.

13. DIRECTIONS FOR USE OF EYEGLASSES:

The ML 830® is a Class IIIb laser that poses a significant potential for eye damage if the laser is directed toward the unprotected eye. Protective glasses are provided with the ML 830® Laser System and must be worn by patients and operators.

Prior to each use, the ML 830® Laser probe should be checked for energy level on the Recharger unit in accordance with the Operating Instructions. Remove the protective glasses provided from the ML 830® carrying case. Place one pair on the patient and one pair on the operator. Do not remove glasses until treatment is completed.

14. TREATMENT REGIMEN:

The laser probe should be placed directly over the area to be treated with the "notch" on the laser head at the 12 o'clock position. Activate the black switch on the laser probe. All lasers are activated first by depressing the switch by gently squeezing. Once the switch is pressed, the laser is activated for one (1) 33-cycle or until the switch is lightly depressed again. Refer to the Treatment Regimen Protocol provided in the Appendix A of this manual.

15. CARE AND MAINTENANCE:

- Cleaning Laser Port: To clean the laser port, lightly moisten a lint-free cloth with 70% solution of rubbing alcohol. Gently dab laser port with the moistened cloth until clean.

- Cleaning Laser Probe: To clean the laser probe, lightly moisten a lint-free cloth with 70% solution of rubbing alcohol and gently wipe the laser diode lenses to remove any potential residue or film. Wipe the outer surface of the laser probe with a lint-free soft cloth to remove any dust or film that may build up on the outside of the laser probe.

NOTE: DO NOT APPLY LIQUID DIRECTLY ON THE LASER PORT, LASER PROBE OR BATTERIES.

16. TECHNICAL INFORMATION:

| DESCRIPTION | MODEL 830 LASER |
|---|---|
| Laser Diodes | GaAlAs |
| Regulatory Class | IIIb |
| Wavelength | 830 nm |
| Norminal Power | 3 x 30 mW continuous wave(cw) |
| Energy per Treatment Cycle | 3 x 0.99 Joule |
| Treatment Cycle Duration | 33 seconds |
| Beam Configuration | 1 x 3 m m |
| Laser Dimensions | 2.1 cm diameter x 21.0cm long |
| Laser Weight | 300 gm |
| Laser Energy Fully Charged Battery | Maximum output: 99mW |
| **DESCRIPTION** | **RECHARGER** |
| Voltage | 110/220/240 volts AC |
| Power Consumption | 9 W |
| Charging Current for Batteries | 60 mA |
| Stable Charge Current | 10 mA |
| Fuses | 2 pcs.200 mA located in rear panel |
| Dimension(L x W x H) | 308 x 220 x 80 mm |
| Weight | 2.33 kg |

17. CALIBRATION:

Your ML 830® laser probe was calibrated at the factory to a fixed output of 90 mW +/- 10%, a maximum of 99mW (33mW each diode). The probe testing port in the Recharger was also calibrated at the factory to measure each laser diode's level of radiation output. At least once a year, an authorized person should examine and measure each of the three ML830 diode-testing sensors, using a calibration standard laser probe (or some other certified and reliable measuring device) to measure each censor and make any necessary calibration at that time. Contact MicroLight for the name, address, and telephone number of such an authorized person.

18. LIMITED WARRANTY - First Year

MicroLight Corporation warrants that your new ML 830® Laser System is free from defects in materials and workmanship for a period of one (1) year from the date of original purchase by your dealer.

If you discover a defect, MicroLight Corporation, at its option, will repair, replace or refund your purchase price, provided you return the ML830® during the first year warranty period. You are responsible for shipping, handling and applicable taxes.

General

In the unlikely event your ML 830® Laser is returned for manufacturing defects, please attach your name, address, telephone number and a copy of your Bill of Sale. Return the product with transportation charges prepaid to our Customer Service Office.

This warranty does not apply if the product has been damaged by accident, abuse, misuse or misapplication, or if the product has been modified without written permission from the Company, or if any serial number has been removed or defaced.

Do not open the laser diode housing of the laser probe or the warranty is void.

MicroLight Corporation is not responsible for special, incidental or consequential damages resulting from any breach of warranty, or under legal theory, including but not limited to lost profits, downtime, goodwill, damage to or replacement of equipment or property.

*EXCEPT AS SPECIFICALLY SET FORTH ABOVE, THE COMPANY DISCLAIMS ANY AND ALL SPECIFIC OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE AND WARRANTIES OF MERCHANTABILITY. THERE ARE NO WARRANTIES WHICH EXTEND BEYOND THE DESCRIPTION SHOWN ABOVE.*

Appendix A

ML 830® Laser Treatment Protocol for CTS

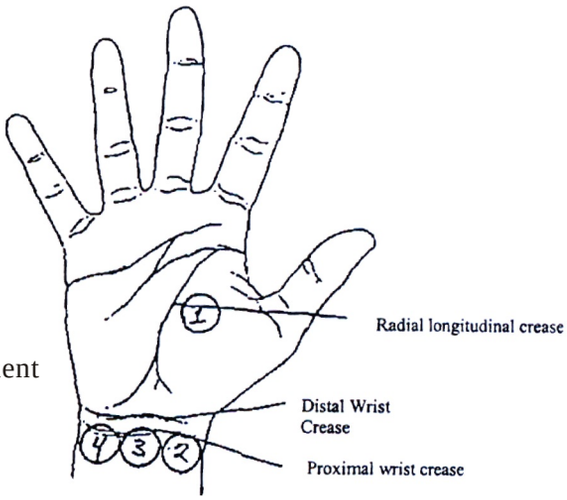
Dose per treatment point: 9 joules (0.99 joule/laser diode x 3 diodes x 3 cycles)

Number of treatment points 4 points (wrist and palm area)

Treatment Intervals: 3 times / week

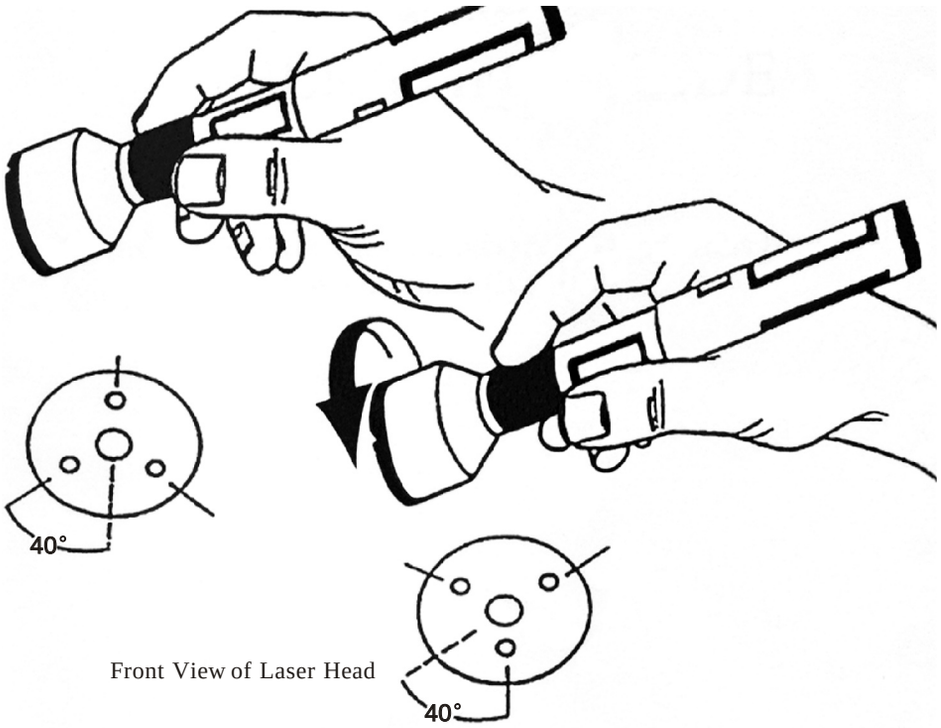
Treatment Session 5 weeks

| Treatment Point | Palmar. Position |
|---|---|
| # 1 | across the thenar muscle between the Radial longitudinal crease and the proximal thumb joint |
| # 2 | Radial side of wrist at the proximal wrist crease across the carpal ligament |
| # 3 | Middle of wrist at the proximal wrist crease across the carpal ligament |
| # 4 | Ulnar side of wrist at the proximal wrist crease across the carpal ligament |



The ML 830® Laser Probe should be applied as follows:

1. Place the Laser Probe to the area to be treated.
2. Activate the Laser beam by depressing the switch (beneath the black vinyl area on the laser which surrounds the entire circumference of the laser probe). The laser diodes are now activated and the switch may be released.
3. Laser energy is emitted for 33 seconds (one cycle), which is equivalent to 0.99 joules of energy per laser diode or 3 joules of accumulative energy.
4. The probe has an audible radiation signal in the form of an acoustic beep during the activation cycle.
5. At the end of the 33-second cycle, the laser automatically switches off and the beep is replaced by one continuous tone for 2 seconds.
6. During the 33-second cycle the laser should be held completely still and in direct contact with the tissue. The same treatment point should be maintained for three cycles, rotating the laser head 40 degrees after each cycle to ensure full coverage of the target point.




Laser Rotation - 40 Degrees